K120423

510(k) SUMMARY
Bionime Rightest Blood Glucose Monitoring System, Model GM650

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92(C)

AUG 3 2012

The Assigned 510(k) number is: _____

Date of Summary: February 9th, 2012

Common Name: Rightest™ Blood Glucose Monitoring System, Model GM650

Regulatory Information:

Product Code	Classification	Regulation Section	Panel
NBW; System, Test, Blood Glucose, Over-the-Counter	Class II	21 CFR 862.1345	75 – Chemistry
LFR; Glucose Dehydrogenase, Glucose	Class II	21 CFR 862.1345	75 – Chemistry
JJX; single (specified) analyte controls (assayed and unassayed)	Class I	21 CFR 862.1660	75 – Chemistry

Applicant:

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Taichung City, Taiwan 412
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Contact Persons:

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510(k) SUMMARY (Cont.)

Identification / Product Name:

Blood Glucose Monitoring System

Device Description:

Our Blood Glucose Monitoring System consists of a Meter, Blood Glucose Test Strips, Three Control Solutions, Lancing Device and Lancets.

The Rightest Meter, Blood Glucose Test Strips, and Lancing Device are manufactured by BIONIME Corporation. The Rightest Meter, when used with the Rightest Test Strips Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System is verified by the Control Solution.

Intended Use:

The Rightest Blood Glucose Monitoring System, Model GM650 is intended for in vitro diagnostic use (outside of body). It is indicated to be used by a single user at home to measure the glucose concentration as an aid to monitor the effectiveness of diabetes control. The glucose concentration is measured with quantitative capillary whole blood (from the fingertip, palm, and forearm), by using Rightest Blood Glucose Monitoring System, GM650.

This device is not intended for testing neonate blood samples and is not intended for the diagnosis of or screening for diabetes mellitus. And this device should not be used for testing multiple patients. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

Rightest Blood Glucose Test Strips GS650 are intended for use with the Rightest Blood Glucose meter GM650 in the quantitative measurement of glucose in capillary whole blood from the fingertip, palm and forearm.

Rightest Control Solutions GC650 are intended for use with the Rightest Blood Glucose Monitoring System, Model GM650 to check that both the glucose meters and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

Predicate Kit:

The Bionime Diabetes Management System is substantially equivalent to the predicate device noted below:

Device Name: Rightest™ Blood Glucose Monitoring System, Model GM550

510k No.: k092052
Device Company: Bionime Corporation

Technology Characteristics:

Bionime's Rightest™ GM650 system is an electronic device that utilizes the electrical characteristic technology for measuring the glucose level in human blood. A relatively small drop of blood is placed on a disposable test strip coated with FAD-glucose Dehydrogenase (FAD-GDH) which interacts with the software driven digital talking meter. Within five seconds, the level of blood glucose will be shown on the digital display screen.

Rightest™ Blood Glucose Monitoring System, with an auto-coding feature, requires only minimum of 1 microliter of blood for the testing, therefore it reduces the time and effort required for testing and improves the compliance of diabetic people to their testing regimens.

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of the Rightest Blood Glucose Monitoring System. The evaluation included precision, linearity, interference and hematocrit.

Discussion of Clinical Tests Performed:

System Accuracy Study:
The accuracy study of the Rightest™ Blood Glucose Monitoring System Model GM650 was performed by comparing whole blood (plasma equivalent) glucose values on the Rightest™ meter with plasma glucose values on a lab instrument.
A total of 118 patients were participated. The study result demonstrates that the accuracy of Rightest™ Blood Glucose Monitoring System Model GM650 met the acceptance criteria.

User Performance Study:
A User performance study was performed to demonstrate that lay consumers could obtain accurate results using the subject device. The study was performed by 161 consumers testing capillary whole blood from fingertip, palm and forearm sample sites. The study result shows substantial equivalence to Rightest Blood Glucose Monitoring System used in finger, palm and forearm position.

Performance:

The results of aforementioned studies demonstrate satisfactory performance of Bionime Rightest™ Blood Glucose Monitoring System GM650, and the device is easy to use and the results are understandable by the target users.

Conclusion:

The results of the verification and validation studies of the Bionime Diabetes Management System demonstrated that the product is safe and effectiveness in the hands of lay users and health care professionals. The product is substantial equivalence to the predicate device, Rightest Blood Glucose Monitoring System Model GM550.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Bionime Corporation
c/o Feng-Yu Lee
IVDD Regulatory Consultant
27001 La Paz Road, Suite 266B
Mission Viejo, CA 92691

AUG 3 2012

Re: k120423
Trade Name: Bionime Rightest™ Blood Glucose Monitoring System, Model GM650
GE Talking Blood Glucose Monitoring System, Model GE300
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: July 9, 2012
Received: July 23, 2012

Dear Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k120423

Device Name: **Rightest Blood Glucose Monitoring System, Model GM650**

Indications For Use:

The Rightest Blood Glucose Monitoring System GM650 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole samples drawn from the fingertips, palm and forearm. The Rightest Blood Glucose Monitoring System GM650 is intended for single patient use only.

The Rightest Blood Glucose Monitoring System GM650 is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM650 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strip GS650 is for use with the Rightest Blood Glucose meter GM650 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The Rightest Control Solution Set GC650 is for use with the Rightest Blood Glucose meter GM650 and Rightest Blood Glucose Test Strips GS650 to check that the meters and test strip are working together properly and that the test is performing correctly.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K120423

Indications for Use

510(k) Number (if known): k120423

Device Name: **GE talking blood glucose monitoring system, Model GE300**

Indications For Use:

The GE talking blood glucose monitoring system Model GE300 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole samples drawn from the fingertips, palm and forearm. The GE talking blood glucose monitoring system Model GE300 is intended for single patient use only.

The GE talking blood glucose monitoring system Model GE300 is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE talking blood glucose monitoring system Model GE300 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The GE300 Blood Glucose Test Strip is for use with the GE talking blood glucose monitoring system Model GE300 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm or forearm.

The GE300 Control Solution Set is for use with the GE talking blood glucose monitoring system Model GE300 and GE300 Blood Glucose Test Strips to check that the meters and test strip are working together properly and that the test is performing correctly.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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